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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO

UNITED STATES OF AMERICA, ex rel. CAMPIE and CAMPIE et al.,

Plaintiffs,

vs.

GILEAD SCIENCES, INC.

Defendant.

Case No. 3:11-cv-00941-EMC

RELATORS' OPPOSITION TO THE UNITED STATES' MOTION TO DISMISS [DOC. 183]

Date: August 1, 2019
Time: 1:30 p.m.
The Honorable Edward M. Chen
Courtroom 5, 17th Floor

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Plaintiffs/Relators Jeff and Sherilyn Campie (collectively, "Relators") respectfully oppose the motion of the United States of America ("the Government") seeking summary dismissal of the non-retaliation federal False Claims Act ("FCA") claims asserted by Relators against Defendant Gilead Sciences, Inc. ("Gilead"). The Government's bid to fully exonerate Gilead from all FCA liability fails to satisfy the fundamental standards for dismissal under 31 U.S.C. § 3730(c)(2)(A) as established by the Ninth Circuit in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.* (*"Sequoia Orange"*), 151 F.3d 1139 (9th Cir. 1998). Relators' opposition to the Government's dismissal motion is supported by the Declaration of Andrew S. Friedman ("Friedman Decl."), the Declaration of Paul Wiener ("Wiener Decl."), the following Memorandum of Points and Authorities, and the Court's file in this case.

I. FACTUAL BACKGROUND

While working as Gilead's Senior Director of Global Quality Assurance, Relator Jeff Campie discovered that [redacted] After Mr. Campie objected, [redacted]

After voicing his concerns to Gilead management, Mr. Campie was first ostracized within the company, and then terminated in July, 2009. Mr. Campie and his wife Sherilyn (also a Gilead employee) in August 2010 commenced this FCA action, alleging that Gilead was submitting false claims to secure hundreds of millions of dollars in reimbursements for the adulterated Truvada and Atripla drug products through numerous Government direct-funding and reimbursement programs, including Medicare, Medicaid, TRICARE, and the Ryan White HIV/AIDS Program. Relators also

alleged related federal and state retaliation claims (which the Government has not moved to dismiss).

After Mr. Campie was fired and initiated this action, he learned that [redacted] Mr. Campie promptly reported these new developments to the Government as well.

In its dismissal motion, the Government asserts that in response to Relators' actions the FDA investigated Gilead's use of the Chinese-sourced API. United States' Motion to Dismiss Relators' Second Amended Complaint [Doc. 183 ("MTD")], at ECF 6-7. The actual scope and specific findings of that investigation remain enshrouded in secrecy, however, despite Relators' requests for this information. Friedman Decl. ¶ 12. This much is clear, though: [redacted]

[redacted] 2014 when Gilead was forced to recall [redacted] $130 million worth of Atripla (39,223 bottles) and of Truvada (10,317 bottles), [redacted] Wiener Decl., [redacted] Ex. 22, and Ex. 23. During an investor conference call on March 6, 2014, Gilead specifically attributed the Atripla recall to contaminated API obtained from Synthetics China. *Id.*, Ex. 23. Nevertheless, [redacted] Gilead retained all funds the Government paid Gilead [redacted]

In short, the uncontested record – [redacted] which, ***at the absolute minimum***, included: [redacted]. The Government has recovered substantial sums under the FCA based on the knowing distribution of adulterated drug products, such as a $500 million FCA settlement with drug maker Schering Plough Corporation and another with drug maker Ranbaxy. Wiener Decl. ¶ 50, Ex. 25; Friedman Decl. ¶ 16, Ex. G-1.

II. PROCEDURAL BACKGROUND

After filing their original complaint, Relators provided the Government with voluminous supporting documents and multiple supplemental disclosure statements. Friedman Decl., ¶ 3. In January 2013, the Government declined to intervene in the Relators' action – a pivotal event under the FCA's statutory scheme. *See*, *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 746 (9th Cir.

1993) ("When the government chooses not to take over a qui tam action, the relator 'shall have the right to conduct the action.'") (quoting 31 U.S.C. § 3730(c)(3)). Among other things, in such case the relator's interest in a share of the recovery increases, and the relator may in addition recover an amount for reasonable expenses, attorneys' fees and costs, awarded against the defendant rather than taken out of the proceeds or settlement. *Kelly*, 9 F.3d at 747. Notably, when the Government initially elects not to take over the action, the court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." *Id.* at 746 (quoting 31 U.S.C. § 3730(c)(3)). In permitting such late intervention, however, the court ***may not*** limit "the status and rights" of the relator. *Id.*

Relators accordingly assumed full responsibility for litigating the FCA action against Gilead, diligently opposing Gilead's successive motions to dismiss the First Amended Complaint ("FAC") and the substantially streamlined Second Amended Complaint ("SAC"). Friedman Decl. ¶ 4. Despite completion of the same investigation on which its current motion to dismiss is premised, the Government in both instances notably remained ***emphatically neutral*** on the factual merit of Relators' FCA claims, while ***steadfastly opposing*** Gilead's legal grounds for dismissal. Friedman Decl. ¶ 5; *see, e.g.*, "United States' Statement of Interest on Defendants' Motion to Dismiss Second Amended Complaint [Doc. 129], at ECF 2 n.1 (emphasizing that the Government's decision to decline intervention "should not be interpreted as a statement on the merits").

In its briefing before Ninth Circuit, the Government again argued against dismissal of Relators' FCA claims while explicitly taking "no position … on whether the allegations in plaintiffs' complaint are sufficient to survive dismissal." Friedman Decl., Ex. A, at ECF 7. The Ninth Circuit ultimately reversed the Court's dismissal orders and reinstated all of Relators' FCA claims. *United States ex rel. Campie v. Gilead Sciences., Inc.*, 862 F.3d 890 (9th Cir. 2017). The Ninth Circuit's published opinion in *Campie* is widely regarded as an important decision in FCA "materiality" jurisprudence, for it confirms the potential for FCA liability notwithstanding continued payment by the Government. *Campie*, 862 F.3d at 906-907. The Government and Relators thus both benefited from the Ninth Circuit opinion, which placed Gilead at risk for hundreds of millions of dollars in FCA exposure in this action.

When Gilead filed a petition for certiorari, the United States Supreme Court called on the Government for its view as to the soundness of the Ninth Circuit's opinion sustaining the FCA claims. Friedman Decl. ¶ 7. In its brief to the Supreme Court, the Government once again defended the legal viability of the Relators' claims, endorsing the Ninth Circuit's legal analysis in *Campie* as completely sound and undeserving of certiorari. Friedman Decl., Ex. B ("CVSG Brief"). The Government specifically emphasized that FCA liability can exist where the Government "may have investigated and found past violations but believe (perhaps incorrectly) that the defendant will comply going forward." CVSG Brief, at 12-13. As explained above, this very scenario is implicated by Relators' FCA allegations against Gilead in this action.

However, in a widely reported "bombshell" announcement – made with no prior notice to the Relators – the Government in the same CVSG Brief stated for the first time that it had decided that continued prosecution of Relators' FCA action against Gilead was suddenly "not in the public interest," and that it would, upon remand, move to dismiss the case under Section 3730(c)(2)(A). CVSG Brief, at 15. Consequently, after nine years of hard-fought litigation in which the Government filed multiple statements supporting Relators' legal arguments while remaining agnostic on the factual merits, Relators' FCA action was suddenly targeted for dismissal – not by Gilead, but by the very Government on whose behalf Relators are seeking to recoup potentially hundreds of millions of dollars in payments for adulterated drugs [redacted]

As shown below, there is no rational justification for the Government's abrupt, about-face decision to exonerate Gilead from FCA liability on the heels of the Ninth Circuit success and in light of its own investigative findings.

III. THE GOVERNMENT'S MOTION TO DISMISS

As the Government concedes, *Sequoia Orange* establishes the controlling standard in the Ninth Circuit for Government dismissal requests under Section 3730(c)(2)(A). MTD, at ECF 10-11. The Government must therefore (1) identify a "valid government purpose" for dismissing the case, and (2) show a "rational relationship between dismissal and accomplishment of the purpose." *Id.* (quotations omitted). Should the Government satisfy this two-step test, "the burden switches to the

relator to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." *Id.*

When moving to dismiss under Section 3730(c)(2)(A) in other actions, the Government has not been shy about identifying the lack of merit as a basis for dismissal. *See, e.g.,* Friedman Decl. ¶ 13 and Ex. F. Yet here the Government conspicuously does not exonerate Gilead or otherwise make any assertion that Relator's FCA claims lack merit; for purposes of its motion to dismiss, therefore, the Government ***presumes*** the merit of Relator's FCA claims against Gilead. [redacted]

Instead, the Government has identified "conserving scarce resources" as its stated purpose in foregoing hundreds of millions of dollars in meritorious FCA claims. MTD, at ECF 15:11-13. According to the Government, summary dismissal would accomplish this stated purpose in two ways. First, the Government says dismissal would "avoid the additional expenditure of government resources on a case that it fully investigated and decided not to pursue." *Id.*, at ECF 12:3-5. In other words, although its motion is based on the same information known to the Government when it repeatedly ***supported*** the legal viability of Relators' FCA claims, the Government is now suddenly concerned about the future costs it may incur in simply ***monitoring*** Relators' continued prosecution of the claims against Gilead. *Id.*, at ECF 12-13. Second, the Government speculates that summary dismissal is needed because both parties "may well [serve it with] burdensome discovery and requests pursuant to *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951)." *Id.*, at ECF 13:9-11.

Finally, the Government in its motion also suggests that summary exoneration of Gilead is necessary to prevent Relators from somehow "undermining" the enforcement decisions the Government made [redacted] MTD, at ECF 14:3-19. The Government does not identify, however, just what "enforcement decisions" it claims would be undermined by the continuation of Relators' FCA action against Gilead. And in fact, Relators have never called for any change in action or position by the FDA as a premise for their claims under the FCA. Nor does the Government present any evidence

that it made a knowing decision [redacted] as opposed to its (unchallenged) decision to allow Gilead to continue to manufacture and distribute presumably compliant drug products.

IV. LEGAL ARGUMENT

A. The Government Has Not Satisfied *Sequoia Orange*'s Standard for Dismissal

As shown below, none of the Government's purported reasons is sufficiently plausible to pass muster under *Sequoia Orange*'s "rational relationship" test. *United States ex rel. Sequoia Orange Co. v. Sunland Packing House Co.*, 912 F. Supp. 1325, 1341 (E.D. Cal. 1995) (there must be "plausible, or arguable, reasons supporting the agency decision"); *accord*, *Lockary v. Kayfetz*, 917 F.2d 1150, 1155 (9th Cir. 1990) ("[T]he rational relation test will not sustain conduct by state officials that is … irrational or plainly arbitrary."). Notably, action taken by an agency without sufficient explanation is by definition arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.* ("*State Farm*"), 463 U.S. 29, 48 (1983) (citations omitted) ("We have frequently reiterated that an agency must cogently explain why it has exercised its discretion in a given manner."). As the Supreme Court held in *State Farm*:

> There are no findings and no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such … practice…. Expert discretion is the lifeblood of the administrative process, but unless we make the requirements for administrative action strict and demanding, ***expertise***, the strength of modern government, can become a monster which rules with no practical limits on its discretion.

463 U.S. at 48 (quotations omitted; emphasis original).

Here, the Government's cursory recital of its three reasons for summary dismissal of Relators' FCA claims suffers the same fatal flaw.

1. The Government's Unsubstantiated Reliance on Future Monitoring Costs

Continued monitoring is an option available to the Government whenever it declines to intervene in a private FCA action, and thus the Government may incur some level of monitoring costs in every such case (the amount of which is completely within its own control). What, then, is the rationale for concluding that the monitoring costs in ***this*** case, at ***this*** juncture, suddenly warrant

dismissal of all FCA claims against Gilead, [redacted] The Government doesn't say. Indeed, the Government makes no effort to estimate or quantify its anticipated monitoring costs, let alone conduct ***any*** cost-benefit analysis to place them in the context of the Government's potential recovery through the FCA claims to be litigated at Relators' expense. *But see*, *State Farm*, 463 U.S. at 43 ("the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made'") (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)); *accord, Ctr. v. Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198-1200, 1203 (9th Cir. 2008) (finding agency reasoning arbitrary and capricious for failure to conduct proper cost-benefit analysis; in conducting the cost-benefit analysis, the agency "cannot put a thumb on the scale by undervaluing the benefits and overvaluing the costs…"); *California v. Azar*, Nos. 19-cv-01184-EMC, 19-cv-01195-EMC, 2019 WL 1877392, at *41 (N.D. Cal. Apr. 26, 2019) ("In the absence of any attempt by [the agency] to quantify or even explain with any substantive analysis the Final Rule's claimed benefits, it cannot be said that there has been a 'reasoned determination' that the benefits justify the costs.").

The Government's glaring lack of any meaningful cost-benefit analysis is deliberate, for it comes in the face of this Court's refusal to accept the Government's similarly unsubstantiated, unanalyzed cost assertions in *Academy Mortgage*, wherein the Government's submission was likewise bereft of any meaningful analysis of either expected monitoring costs or expected gains. *United States v. Acad. Mortg. Corp.* (*"Academy Mortgage"*), No. 16-cv-02120-EMC, 2018 WL 4794231, at *3 (N.D. Cal. Oct. 3, 2018) (Chen, J.) ("the Government's assertion that proceeding with the case would be unduly costly was undermined by evidence submitted by the Relator showing that the Government had not meaningfully considered what the cost of the suit might be"). Indeed, at the last status conference before this Court, the Government, while acknowledging the Court's ruling in A*cademy Mortgage*, announced itself prepared to present the Court with the necessary evidentiary showing to support dismissal under *Sequoia Orange*. Friedman Decl. Ex. D, at 15:15-19. (Ms. Winslow, for the Government: "Our position, I'm sure, is going to be that there shouldn't be an

evidentiary hearing and we would provide the evidence I think you need. I think counsel is absolutely correct, that this was a very different investigation than the *Academy Mortgage* case.").

Yet the Government has chosen not to present any cost-benefit analysis to the Court here, nor any facts from which any such analysis could be conducted. *See also, United States ex rel. CIMZNHCA, LLC v UCB, Inc.* ("*CIMZNHCA*"), No. 17-CV-765-SMY-MAB, 2019 WL 1598109, at *3 (S.D. Ill. Apr. 15, 2019) (failure of the Government to conduct a meaningful cost-benefit analysis which assessed or analyzed the costs it would likely incur versus the potential recovery that would flow to the Government if this case were to proceed "falls short of a minimally adequate investigation to support the claimed governmental purpose"). As the court explained in *CIMZNHCA*,

> While the Government suggests it need only identify such an interest [in avoiding litigation costs] to satisfy the *Sequoia Orange* standard, the Court's inquiry does not end there. For the Government's stated purpose to be valid and for there to be a rational relationship between it and the dismissal, its decision to dismiss must have been based on a minimally adequate investigation, ***including a meaningful cost-benefit analysis***.

2019 WL 1598109, at *3 (emphasis added). The *CIMZNHCA* court accordingly denied the Government's motion to dismiss the relator's FCA claims, even though there (unlike here) the Government had concluded the alleged FCA claims lacked merit. *Id; see also*, Friedman Decl. ¶ 15.

Not only that, but the Government ***itself*** internally recognizes the need to place such monitoring cost contentions in proper context when seeking dismissal of an FCA action under Section 3730(c)(A)(2). Since January 2018, Government policy with respect to the dismissal of FCA actions has been memorialized in a DOJ Memorandum authored by Michael D. Granston entitled "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)." Friedman Decl., Ex. C ("the Granston Memo"). Describing itself as "intended to provide a general framework for evaluating when to seek dismissal under section 3730(c)(A)(2) and to ensure a consistent approach to this issue across the Department," the Granston Memo identifies seven factors that, "to ensure consistency across the Department," should "serve as a basis for evaluating whether to seek to dismiss future matters." Granston Memo, at 2. With respect to the pertinent Granston Memo factor here – "Preserving Government Resources" – the Government explicitly states: "The Department should also consider dismissal under section 3730(c)(2)(A) when the government's expected costs ***are likely to exceed***

any expected gains." *Id.*, at 6 (emphasis added). [1]

Furthermore, the Granston Memo was "intended to provide a general framework for evaluating when to seek dismissal under section 3730(c)(A)(2) and to ensure a ***consistent*** approach to this issue across the Department," identifying seven factors that "serve as a basis for evaluating whether to seek to dismiss future matters" in order to "ensure ***consistency*** across the Department." Granston Memo, at 2 (emphasis added). Yet the Government violated its own consistency guidelines with respect to the "Preserving Government Resources" factor, by failing to seek dismissal based on an assessment of both the "expected costs" ***and*** the "expected gains."

In short, both the courts and the Government have recognized that premising a dismissal request on generalized references to unquantified, purely speculative future monitoring costs – without any consideration of the benefit side of the equation – is not a rational exercise of prosecutorial discretion and therefore insufficient to satisfy the Ninth Circuit's *Sequoia Orange* standard. *See*, *Academy Mortgage*, 2018 WL 4794231, at *3 (denying motion to dismiss where the Government failed to make even a cursory showing that it had considered the potential proceeds from the litigation, which the court called "a central factor in the cost analysis"); *CIMZNHCA*, 2019 WL 1598109 at *3 (likewise denying the Government's motion to dismiss; for failure to conduct the meaningful cost-benefit analysis required under *Sequoia Orange*). *See generally*, *United States v. Redondo-Lemos*, 955 F.2d 1296, 1299 (9th Cir. 1992) ("[I]t would offend common notions of justice to have [charging decisions] made on the basis of a dart throw, a coin toss or some other arbitrary or capricious process."), *overruled on other grounds by, United States v. Armstrong*, 517 U.S. 456 (1996)). Because there will be some monitoring cost in ***every*** FCA case in which the Government declines to intervene, it is arbitrary and capricious to use that factor as the reason to single out ***this*** case for dismissal.

[1] Tellingly, not only does the Government fail to assert or demonstrate that Relators' claims are "meritless," it likewise fails to assert any of the following grounds for dismissal articulated in the Granston Memo: (1) that this is a "parasitic" or "opportunistic" *qui tam* action; (2) that this case interferes with the Government's control of related litigation; (3) that dismissal is necessary to safeguard classified information; or (4) that this action would interfere with ongoing regulatory investigations if allowed to continue. Granston Memo, at 3-7.

2. The Government's Unsubstantiated Fear of Potentially Burdensome Discovery

The Government's other stated concern -- that the parties "may well file burdensome discovery and [*Touhy*] requests" -- is on its face utterly speculative and necessarily arbitrary at this stage, where no party has served even a single discovery request to the Government. Notably, neither of the two declarations submitted by the Government comes close to addressing, let alone supporting, the abstract prospect of onerous future discovery. Instead, the Government simply ***assumes*** that it will face burdensome discovery on the issue of materiality under the FCA, asserting that the parties "likely will" seek discovery as to "exactly what the government knew and when." MTD, at ECF 13:11-15. This purported fear of undue discovery burden is unfounded, unsubstantiated, and implausible on multiple levels.

First, it is not at all clear that – in the context of this particular action – there will necessarily be ***any*** discovery demands regarding materiality placed on the Government. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property," 31 U.S.C. § 3729(b)(4), and the Supreme Court has accordingly adopted an ***objective test of materiality***. *Universal Health Servs., Inc. v. United States* ("*Escobar*"), 136 S. Ct. 1989, 2002-03 (2016). In *Escobar*, the Court held the materiality analysis under the FCA can be conducted from the perspective of a reasonable person, specifically alluding to the objective "reasonable man" standards under tort and contract law. *Id.* at 2004 n.6 ("The standard for materiality that we have outlined is a familiar … one."). The *Escobar* Court accordingly emphasized that materiality was therefore not necessarily determined by the Government's conduct:

> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.

Id. at 2003. As the Supreme Court recognized in *Escobar*, proof of materiality includes, but is not limited to, "evidence that the ***defendant knows*** that the Government consistently refuses to pay claims" in cases based on noncompliance with a particular statutory or regulatory requirement. *Id.* (emphasis added); *see, e.g., United States ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1020 (9th Cir

2018) ("A reasonable trier of fact could find materiality here because the Department's payment was conditioned on compliance with the incentive compensation ban, because of the Department's past enforcement activities, and because of the substantial size of the forbidden incentive payments.").

Thus, proof of materiality can come from sources other than the testimony of Government witnesses, including from the defendant itself. Here, materiality can similarly be established through Gilead's own behavior, such as [redacted]

Moreover, materiality can alternatively be established based on mandatory, unqualified statutory prohibitions alone. In *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008), for example, the Seventh Circuit held that omissions in the defendant hospital administrator's Medicare and Medicaid reimbursement claims, which failed to disclose that illegal referrals had occurred or that kickbacks had been paid, were "material" for purposes of the government's FCA claims against hospital administrator because the Stark Amendment barred payment of claims arising from medical services rendered to improperly referred patients. The court swiftly debunked the defendant's argument that, despite the statutory prohibition, "a federal employee in a position to take a decision had to testify that the government was sure to enforce the statute":

> That's not a component of materiality. A statement or omission is "capable of influencing" a decision even if those who make the decision are negligent and fail to appreciate the statement's significance. *** The question is … whether the omission could have influenced the agency's decision. That's an objective standard, here controlled by the Stark Amendment. Testimony from a claims-processing officer along the lines of "I follow the law" is not required.

517 F.3d at 452. Here, likewise, the federal FDCA strictly prohibits the placement of adulterated drug products into the stream of commerce. 21 U.S.C. §§ 331, 334. There is no call or need for any discretionary determination by the FDA. Under these circumstances, the testimony of a federal witness is not likely required to prove that the Gilead drug products' very status as ***contraband*** under federal law would have "a natural tendency to influence, or be capable of influencing, the payment

or receipt of money" to satisfy the materiality standard under FCA Section 3729(b)(4).

Second, the Government's ill-defined and unsubstantiated concern of some hypothetical undue burden would not be sufficient even to support the issuance of a garden-variety protective order under Fed. R. Civ. P. 26(c), let alone to warrant the "nuclear option" of summary dismissal of all Relators' FCA claims. *See, e.g., Blankenship v. Hearst Corp.*, 519 F.2d 418, 429 (9th Cir. 1975) (a party seeking a protective order must make a clear showing of a particular and specific need for the order); *Lexington Ins. Co. v. Sentry Select Ins. Co.*, No. 1:08-cv-1539 LJO GSA, 2009 WL 4885173, at *3 (E.D. Cal. Dec. 17, 2009) (conclusory or speculative statements about the need for a protective order and the harm that will be suffered without one are insufficient). Airy and unfocused assertions of harm in a brief – unsubstantiated by specific examples or articulated reasoning – are an inadequate basis for judicial action. *Foltz v. State Farm Mut. Auto. Ins. Co.*, 331 F.3d 1122, 1130 (9th Cir. 2003).

Third, the Government dramatically understates the degree of control it retains over its participation in discovery in this case. Because the Government argues that it need not intervene to secure summary dismissal,[2] it is not presently a party subject to direct discovery requests under Fed. R. Civ. P. 30-34; instead, Relators and Gilead must secure information only through subpoenas, to which the Government may assert burdensomeness objections just as any other person. *Exxon Shipping Co. v. U.S. Dep't of Interior*, 34 F.3d 774, 780 (9th Cir. 1994) ("[D]istrict courts should apply the federal rules of discovery when deciding on discovery requests made against government agencies * * *. Under the balancing test provided by the rules, courts can ensure that the unique interests of the government are adequately considered."). If the Government feels unduly burdened by a particular discovery request as the litigation progresses, therefore, the Court has ample tools short of complete dismissal to alleviate that burden, including protective orders of practically

[2] Relators reserve for appellate review their right to challenge the notion that while under the FCA the Government clearly must intervene to ***settle*** a relator's FCA claims, it need not intervene to ***dismiss*** a relator's FCA claims. *Sequoia Orange*, 151 F.3d at 1145 (noting that § 3730(c)(2)(A) "***may*** permit the government to dismiss a qui tam action without actually intervening in the case at all")(emphasis added); *but see*, *United States ex rel. Eisenstein v. City of New York, New York*, 556 U.S. 928, 933 (2009) (absent intervention, the United States is not considered a party to the FCA action).

unlimited nature and scope. Fed. R. Civ. P. 26(c)(1); *see also*, Fed. R. Civ. P. 26(b)(1) (limiting discovery to "nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case"). This would, again, only be a matter of last resort: Relators have found no reported case within the Ninth Circuit in which the non-party Government was compelled to seek such a protective order in an FCA action in which it had declined to intervene.

Finally, to whatever extent the Government seriously contends the FDA's *Touhy* regulations are implicated in this action notwithstanding *Exxon Shipping* (*see* MTD, at ECF 13 (citing *Touhy*)), those regulations purport to vest so much control in the FDA and CMS that any testimony obtained thereunder is ***by definition*** not unduly burdensome to the Government. 21 C.F.R. §§ 20.1 and 20.2. For instance, with respect to the production of witnesses, an extended quotation from Section 20.1 is apropos:

> (a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.
>
> (b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.
>
> (c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: *Provided*, That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

21 C.F.R. § 20.1 (emphasis in original). Thus, under the FDA's *Touhy* regulations only on terms

essentially ***dictated by the Government*** would any FDA or CMS employee be made available for testimony, either in discovery or at trial. And the FDA's *Touhy* regulation essentially converts any subpoenas duces tecum into a FOIA request. 21 C.F.R. § 20.2.[3] Federal agencies are not especially known for cooperating with FOIA requests, which furthermore (a) are subject to much broader grounds for objection than subpoenas, and (b) do not necessarily yield information in a particularly timely manner. *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978) (since FOIA was not intended to function as a private discovery tool, party had no basis to demand FOIA production in time for use in litigation).

3. The Government's Unsubstantiated Fear of Undermining its Regulatory Decisions

As a final, almost passing argument the Government in two paragraphs asserts that dismissal is necessary to prevent Relators' from "undermining the [Government's] considered decisions … about how to address the conduct at issue here." MTD, at ECF 14 ("Relators' case now asks a jury to find that different action was nevertheless required."). The Government is apparently referring to the FDA's decision not to withdraw FDA approval of Gilead's HIV treatment drugs, because it suggests doing so would entail a rigorous process that includes judicial review. *Id.*

This argument is sorely misguided. No one is calling for withdrawal of FDA approval of any Gilead drug product, or to stop production or otherwise deprive the market of needed drug products like Truvada and Atripla. Indeed, ***Relators do not seek injunctive relief of any kind.*** Nor are Relators seeking the reversal of any regulatory decision made by the FDA against recalling any drug product. Relators instead seek only reimbursement of governmental payments should they establish that Gilead's drug products [redacted] were indeed adulterated contraband and therefore did not qualify for payment under the federal direct-payment and reimbursement programs. Relators' FCA claims are completely consistent with [redacted]

[3] Government regulations that purport to convert subpoenas into FOIA requests have been criticized as going beyond the limitations authorized under *Touhy*. *See, e.g.*, Daniel C. Taylor, "*Taking Touhy Too Far: Why It Is Improper for Federal Agencies to Unilaterally Convert Subpoenas into FOIA Requests*," 99 Geo. L.J. 1227 (2011).

[redacted], which no one can suggest undermines any regulatory action by the FDA.

Not surprisingly, then, the Government's explanation of its new-found purpose in dismissing all FCA claims against Gilead is again fatally cryptic: the Government never clearly discloses or explains exactly what its "considered decisions" were with respect to recovery of its payment for [redacted] and those recalled in 2014. Because the same hopelessly generic assertion of undermining the Government's "considered decisions" would apply in every single FCA case in which the Government has declined to intervene, it provides no basis to dismiss ***this*** particular FCA case against Gilead. *Accord, CIMZNHCA*, 2019 WL 1598109, at *4 (finding Government's naked assertion that continued prosecution of FCA claims by the relator purportedly conflicted with "important policy and enforcement prerogatives of the Government's healthcare programs" to be pretextual, and "curious at best").

Furthermore, it bears special emphasis that, from the moment it declined to intervene in this action and through the release of the Ninth Circuit's favorable decision, the Government did not view the continued prosecution of Relators' FCA action as posing any threat to undermining its "considered decisions." Indeed, based on the same information it has now the Government consistently ***opposed*** dismissal in the district court and ***supported*** reversal at the Court of Appeals, while remaining neutral on the possibility of Relators' factual success on the merits. Freidman Decl. ¶¶ 5-6. The Government doesn't identify any "considered decision" of the FDA reached between the time it submitted its brief to the Ninth Circuit and its CVSG brief to the Supreme Court. If anything, the record presents an ***abrupt change of course*** by the Government, supported *post hoc* by only broad conclusory reasons -- the hallmarks of an arbitrary decision. *Compare Del Monte Dunes at Monterey, Ltd. v. City of Monterey*, 920 F.2d 1496, 1508 (9th Cir. 1990) (actionable claim of arbitrariness stated where city council abruptly changed course, while giving only broad conclusory reasons for the change).

4. The Government's Exoneration of Gilead from All FCA Liability Is Arbitrary and Capricious

Given the fact that [redacted]

[redacted], the Government's bid to exonerate Gilead is at odds with the fundamental purpose of ***both*** the FDCA (prohibiting adulterated drugs as contraband) and the FCA (the recovery of Government payment for delivered goods that were not as specified) – and is accordingly fairly classified as arbitrary and capricious conduct. *See, e.g., Ctr. for Biological Diversity v. Jewell*, 248 F. Supp. 3d 946, 958 (D. Ariz. 2017) (government action at odds with the purposes of the pertinent statute deemed arbitrary and capricious); *Hornbeck Offshore Transp., LLC v. U.S. Coast Guard*, 424 F. Supp. 2d 37, 52 (D.D.C. 2006) (same). Here, under the FDCA the FDA lacks the discretion to turn a blind eye toward such contraband in interstate commerce. 21 U.S.C. §§ 331, 334(a)(1); s*ee, e.g., Cook v. Food & Drug Admin.*, 733 F.3d 1, 9-11 (D.C. Cir. 2013) (the FDA does not have discretion under the FDCA to admit misbranded drugs manufactured by an unregistered foreign establishment); *United States v. 38 Cases, Containing Figlia Mia Brand*, 99 F. Supp. 460, 463 (S.D.N.Y. 1951) ("The purpose of the [FDCA], of which [Section 334] a part, is the protection of the public health and to prevent deception of the purchasing public.") (citing House Report No. 2139, 75th Congress, Third Session).

Because the Government does not in its motion contest the merit of Relators' FCA claims, the question at hand is the arbitrariness of the Government's decision to summarily dismiss those ***presumably*** meritorious claims and thereby forego any recovery whatsoever from Gilead.[4] The Government's motion also severely prejudices the Relators' vested interests in the recovery from Gilead as the settling FCA defendant of the relator's share of the settlement consideration, litigation expenses, attorneys' fees and costs. *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772 (2000) (the FCA "gives the relator himself an interest *in the lawsuit*, and not merely

[4]The notion that Congress intended to establish no standard at all for dismissal by the Government under Section 3730(c)(2)(A) simply cannot be squared with (a) the explicit right of the relator to object to dismissal, (b) the relator's right to request a hearing under Section 3730(c)(2)(A), and (c) the statutory requirement under Section 3730(c)(2)(B) that the Government demonstrate any settlement with the defendant to be "fair, adequate, and reasonable" under the circumstances. Why would a settlement for ***nominal*** consideration require court approval, but a dismissal for ***zero*** consideration not? The only reasonable construction of Section 3730(c)(2) is that the same standard applies to both settlements and dismissals initiated by the Government. Indeed, the same burden applicable to settlements should apply *a fortiori* to a defendant's most prized form of settlement – a voluntary dismissal brokered by the Government after having earlier declined to intervene as of right.

the right to retain a fee out of the recovery") (emphasis in original).

Finally, the Granston Memo states that before moving to dismiss under Section 3730(c)(2)(A) the Government should, "to the extent possible," advise relators of perceived deficiencies in their cases as well as the prospect of dismissal so that relators may make an informed decision regarding whether to proceed with the action. Granston Memo, at 8. Rather than do so, the Government here gave no notice to Relators of its decision to dismiss until sprung on them in its CVSG brief, at that point irrevocably committing the Government to a dismissal while simultaneously gutting any conceivable negotiating leverage for Relators on their FCA claims, including their claims to fees and expenses in litigating the case for nearly a decade. Friedman Decl. ¶ 9. Nor did the Government meet with Relators to assess the Relator's streamlined claims in the SAC, or even the information secured through its investigation (including analysis of any of the "600,000 pages of documents" purportedly reviewed by the Government). *Id.* ¶ 12. Instead, the Government kept Relators in the dark about its intention to dismiss, and then rebuffed Relators' attempts to obtain information relevant to the Government's announced motion to dismiss – including specifically information concerning any discussions between the Government and Gilead concerning dismissal of the Relators' FCA claims. *Id.* ¶¶ 9, 11, and Ex. E, at 1. In particular, the Government did not respond to Relators' written request for information regarding its dismissal decision until after the Government's motion had already been filed with this Court, and then simply parroted the same reasons stated in its motion. *Id.* ¶ 11. The Government's failure to include the Relators as part of the FCA claim assessment process is a further indicator of the fundamental arbitrariness of its actions.

B. The Government Cannot Not Belatedly Supplement Its Evidentiary Submissions

To justify its decision in this instance, the Government has submitted two remarkably conclusory declarations, from Special Agent Russo of the DHHS [Doc. 184] and Assistant Special Agent Scavdis of the FDA [Doc. 185]. As shown above, this extremely meager evidentiary submission reflects a deliberate decision by the Government, made with full awareness of the Court's earlier ruling in *Academy Mortgage*. Under such circumstances, the Government cannot now supplement its own submission for the first time on reply. *See, e.g., Rivera v. Saul Chevrolet, Inc.*,

No. 16-CV-05966-LHK, 2017 WL 3267540, at *6 (N.D. Cal. July 31, 2017) ("the submission of new facts in a reply brief is improper"); *MediaTek Inc. v. Freescale Semiconductor, Inc.*, No. 11-cv-5341 YGR, 2014 WL 2859280, at *4 n.3 (N.D. Cal. June 20, 2014) (same); *Contratto v. Ethicon, Inc.*, 227 F.R.D. 304, 308-09 n.5 (N.D. Cal. 2005) (same; citing *Gold v. Wolpert*, 876 F.2d 1327, 1331 n.6 (7th Cir. 1989) ("It is well settled that new arguments cannot be made for the first time in reply. This goes for new facts too."); *Payne v. Giant Food, Inc.*, 346 F. Supp. 2d 15, 20 n.4 (D.D.C. 2004) ("These facts were raised for the first time in petitioner's reply ... petitioner's effort … to meet his burden … comes too late.") (internal quotations and citation omitted); *Schwartz v. Upper Deck Co.*, 183 F.R.D. 672, 682 (S.D. Cal. 1999) ("It is well accepted that raising of new issues and submission of new facts in [a] reply brief is improper.") (citing *Provenz v. Miller*, 102 F.3d 1478, 1483 (9th Cir. 1996)); *see also, e.g., CIMZNHCA*, No. 17-CV-765–SMY-MAB [Doc. 79], at Friedman Decl. ¶ 15 (denying the Government's attempt to "provide the Court with supplemental information regarding …. the government's cost-benefit analysis…." in support of its motion to dismiss the relators' FCA claims pursuant to Section 3730(c)(2)(A)).

C. Relators' Objection to the Proposed Form of Order

Finally, Relators object to the Government's overbroad proposed form of order (MTD, at ECF 16), which purports to dismiss Relators' entire SAC with prejudice, even though the Government has in fact not moved for dismissal of either (a) Relator's FCA retaliation claims under 31 U.S.C. § 3730 (h), or (b) Relators' state law qui tam and retaliation claims.

In addition, because for purposes of its motion the Government does not contest the merit of Relators' FCA claims, and because there are other related claims remaining to be litigated that should not be in any way prejudiced by the Government's desire to "conserve[] scarce resources," any dismissal of the federal FCA Claims under Section 3730(c)(2)(A) should be made "without prejudice," to preclude any claim or issue preclusion argument by Gilead with respect to those related but unaffected claims.

V. CONCLUSION

For the foregoing reasons, the Court should deny the Government's motion to dismiss for its *prima facie* failure to satisfy the *Sequoia Orange* standard.

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Respectfully submitted,

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